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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,159	06/24/2003	Nebojsa Janjic	NEX66/D2	3567

25871 7590 11/14/2006
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EXAMINER

VIVLEMORE, TRACY ANN

ART UNIT PAPER NUMBER

1635

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,159

Applicant(s)

JANJIC ET AL.

Examiner

Tracy Vivlemore

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/5/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection or objection not reiterated in this Action is withdrawn.

Election/Restrictions

Claims 1-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 16, 2006.

Response to arguments: Claim Rejections - 35 USC § 103

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al. in view of Tullis and Ferns et al. This rejection is maintained for the reasons set forth in the office action mailed May 2, 2006.

Applicants traverse the rejection by arguing that the references do not suggest the desirability of the combination and the examiner uses impermissible hindsight. This rejection is not based on impermissible hindsight, the teachings of Gold et al. of a method for producing nucleic acid ligands to any target and the suggestion to use these ligands to deliver therapeutic agents provide a motivation to use nucleic acid ligands, the teachings of Ferns et al. provide a specific motivation to therapeutically target PDGF by teaching the involvement of this growth factor in restenosis and the teachings of Tullis et al. provide a motivation to conjugate nucleic acids to moieties that improve their solubility.

Applicants further argue there is no reasonable expectation of success in combining the references because the nucleic acid ligands of Gold et al. are not the functional equivalents of the oligonucleotides of Tullis and there would be no expectation of success in substituting nucleic acid ligands into the teachings of Tullis and Ferns et al. Applicants argue there are distinct differences between the oligonucleotides of Tullis, which act through a mechanism of Watson-Crick base pairing, and nucleic acid ligands, which bind to a non-nucleic acid target molecule through a three dimensional interaction. Applicants further argue that because maintenance of the three dimensional structure is essential to the function of nucleic acid ligands, whether the function of the nucleic acid ligand would be maintained after conjugation was completely unpredictable and there thus would be no expectation of success. Applicants cite the size difference between a nucleic acid ligand and PEG, which can be 1,000-1,000,000 Da as a reason that it cannot be predicted whether a conjugate will be active. While applicant is correct that activity of a conjugate may not be predictable, requiring conjugates be tested, an obviousness rejection does not require absolute predictability, merely a reasonable expectation of success. This reasonable expectation of success lies in the teachings of the art that nucleic acid conjugates are known to increase the uptake of nucleic acids. It is recognized that nucleic acid ligands have a different structure and mechanism of action the antisense sequences taught by Tullis, but regardless of their mechanism, the ligands of the invention are nucleic acids and the art teaches that conjugation of nucleic acids to compounds that increase their solubility and uptake was well-known in the art prior to the time of the invention. Applicants themselves state in the remarks traversing the written description rejection, "...the art of

Art Unit: 1635

conjugating Lipophilic Compounds and/or High Molecular Weight Non-immunogenic Compounds to therapeutically active compounds is very well developed." Therefore even though some testing might have to be done, given the teachings in the art of nucleic acid ligands as useful for delivery of therapeutic agents and the teachings that nucleic acid conjugates have increased uptake, the person of ordinary skill in the art would have a reasonable expectation of success in combining the references of Gold et al. and Tullis to make conjugates of nucleic acid ligands and non-immunogenic, high molecular weight compounds such as PEG.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

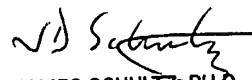
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
November 6, 2006


JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER